



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

March 6, 2005

FILE COPY

Marvin J. Garrett
ISTA Pharmaceuticals
15295 Alton Parkway
Irvine, California

Dear Mr. Garrett:

Your petition requesting the Food and Drug Administration to be consistent on the exclusivity of NDA 21-640 for Vitrase, a proprietary formulation of highly purified ovine hyaluronidase, was received by this office on 04/06/2005. It was assigned docket number 2005P-0134/CP1 and it was filed on 04/06/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Jennie C. Butler, Director
Division of Dockets Management
Office of Management Programs
Office of Management

2005P-0134

ACK 1